Complete Summary

GUIDELINE TITLE

United Kingdom national guideline on the management of trichomonas vaginalis (2007).

BIBLIOGRAPHIC SOURCE(S)

Clinical Effectiveness Group, British Association for Sexual Health and HIV (BASHH). United Kingdom national guideline on the management of trichomonas vaginalis. London (UK): British Association for Sexual Health and HIV (BASHH); 2007. 8 p. [36 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previously released version: Association for Genitourinary Medicine (AGUM), Medical Society for the Study of Venereal Disease (MSSVD). 2002 national guideline on the management of trichomonas vaginalis. London: Association for Genitourinary Medicine (AGUM), Medical Society for the Study of Venereal Disease (MSSVD); 2002. Various p. [22 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Trichomonas vaginalis infection

GUIDELINE CATEGORY

Diagnosis
Management
Treatment

CLINICAL SPECIALTY

Infectious Diseases
Obstetrics and Gynecology
Urology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To assist practitioners in managing men and women diagnosed with *Trichomonas vaginalis*

TARGET POPULATION

Men and women in the United Kingdom, including pregnant women and women who are breastfeeding, with *Trichomonas vaginalis* infection

Note: The guideline is aimed primarily at people aged 16 years or older (see specific guidelines for those under 16).

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

Females:

1. Direct observation (wet smear or acridine orange stained slide from the posterior fornix)
2. Culture
3. Polymerase chain reaction-based test
4. Cervical cytology confirmed preferably by culture

Males:

Urethral culture and or culture of first-void urine

Treatment/Management

1. Simultaneous treatment of sexual partner(s), and sexual abstinence advice
2. Screen for coexistent sexually transmitted infections (STIs)
3. Metronidazole, oral
4. Tinidazole, oral
5. Desensitization for nitroimidazole allergy

6. Management of treatment during pregnancy and breast feeding
7. Management of treatment failure:
    - Assessment for compliance, vomiting, re-infection, treatment of partner
    - Repeat standard treatment
    - Sensitivity testing
    - Treatment with broad spectrum antibiotics (erythromycin or amoxicillin) before re-treating with metronidazole
    - Higher doses of metronidazole (oral, intravaginal, intravenous)
    - High dose tinidazole
    - Alternative treatments with anecdotal support, including 6% nonoxynol-9 pessaries, acetarsol pessaries, and paromomycin sulphate pessaries
8. Management of sexual partners (screening for STIs, treatment)
9. Evaluation of children
10. Follow-up: tests of cure

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of diagnostic tests
- Cure rate

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developers searched Medline for the years 1966-2006 using keywords "*Trichomonas vaginalis*," "trichomoniasis" limited to "human" and "English." They also searched Medline for the years 1966-2006, using keywords "*Trichomonas vaginalis*," "trichomoniasis," and "resistance" limited to "human" and "English." In addition, they searched the Cochrane database on treatment of *Trichomonas vaginalis* in women. They also reviewed the 2006 U.S. Centers for Disease Control and Prevention (CDC) "Guidelines for the Treatment of Sexually Transmitted Diseases" and the *British National Formulary* October 2006.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Ia: Evidence obtained from meta-analysis of randomised controlled trials
Ib: Evidence obtained from at least one randomised controlled trial
IIa: Evidence obtained from at least one well designed controlled study without randomisation
IIb: Evidence obtained from at least one other type of well designed quasi-experimental study
III: Evidence obtained from well designed non-experimental descriptive studies such as comparative studies, correlation studies, and case control studies
IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grading of Recommendations

A (Evidence Levels Ia, Ib)

- Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation.

B (Evidence Levels IIa, IIb, III)

- Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation.

C (Evidence Level IV)

- Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities.

- Indicates absence of directly applicable studies of good quality.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Members of the Clinical Effectiveness Group and the British Association of Sexual Health and HIB (BASHH) had the opportunity of comment on the guideline.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Levels of evidence (I-IV) and grades of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

Diagnosis

Laboratory Investigations

Females

- Direct observation by wet mount or acridine orange staining is approximately 70% sensitive compared to culture in females, but will only detect about 30% cases in males. Microscopy for *Trichomonas vaginalis* should be performed as soon as possible after the sample is taken as motility diminishes with time.
- Culture techniques are still regarded as the most sensitive and specific; they provide the "gold standard" against which other methods are judged. (**III, B**). Culture media vary in efficiency but Diamond's TYM medium (or modified version) is amongst the best.
- Polymerase chain reaction (PCR) based diagnostic tests have recently been developed and sensitivities and specificities approaching 100% have been reported. No PCR assay for *T. vaginalis* is currently on the market in the United Kingdom (UK). (**III, B**)
- Trichomonads are sometimes reported on cervical cytology; however a meta-analysis has shown that while it has good specificity the weighted mean sensitivity was only 58%. In such cases it is prudent to confirm the diagnosis, preferably by culture of vaginal secretions. (**Ia, A**).

Sites Sampled

Females (**III, B**)

- Swab taken from the posterior fornix at the time of speculum examination.
- Self-administered vaginal swabs have been used in many recent studies, and are likely to give equivalent results.

Males (**III, B**)

- Urethral culture or culture of first-void urine will diagnose 60-80% cases; sampling both sites simultaneously will significantly increase the diagnostic rate.

Management

General Advice

Sexual partner(s) should be treated simultaneously. Patients should be advised to avoid sexual intercourse (including oral sex) until they and their partner(s) have completed treatment and follow-up.

Patients should be given a detailed explanation of their condition with particular emphasis on the long-term implications for the health of themselves and their partner(s). This should be reinforced by giving them clear and accurate written information.

Further Investigations

Screening for coexistent sexually transmitted infections (STIs) should be undertaken in both men and women.

Treatment

The frequency of infection of the urethra and paraurethral glands in females dictates that systemic chemotherapy be given to effect a permanent cure. Most strains of *T. vaginalis* are highly susceptible to metronidazole and related drugs (approximately 95% cure rate). There is a spontaneous cure rate in the order of 20-25%.

Recommended Regimes (**IIb**)

- Metronidazole 2 g orally in a single dose

  or

- Metronidazole 400-500 mg twice daily for 5-7 days

The single dose has the advantage of improved compliance and being cheaper; however, there is some evidence to suggest that the failure rate is higher, especially if partners are not treated concurrently.

Alternative Regimens

Tinidazole 2 g orally in a single dose

Tinidazole has similar activity to metronidazole but is more expensive.

Caution

Patients should be advised not to take alcohol for the duration of treatment and for at least 48 hours afterwards because of the possibility of a disulfiram-like (Antabuse® effect) reaction.

Allergy

There is no effective alternative to 5-nitroimidazole compounds. In cases of true allergy, desensitization to metronidazole has been described and could be considered.

Pregnancy and Breast Feeding

Meta-analyses have concluded that there is no evidence of teratogenicity from the use of metronidazole in women during the first trimester of pregnancy (**Ia**). The British National Formulary advises against high dose regimens in pregnancy.

Metronidazole enters breast milk and may affect its taste. The manufacturers recommend avoiding high doses if breastfeeding.

Treatment Failure (IV or anecdotal)

- Check compliance and exclude vomiting of metronidazole
- Check possibility of re-infection
- Check partner(s) has been treated

1. Patients who fail to respond to first course of treatment often respond to a repeat course of standard treatment.

   If this fails and above excluded, the treatment of patients with metronidazole-refractory vaginal trichomoniasis constitutes a major therapeutic challenge, and treatment options are extremely limited. Sensitivity testing is currently unavailable.

2. It has been suggested that some organisms present in the vagina may interact to reduce the effectiveness of nitroimidazole and that use of a broad spectrum antibiotic such as with erythromycin or amoxycillin before re-treating with metronidazole will improve the chances of cure.
3. Higher doses of metronidazole
    a. Metronidazole 400 mg three times daily with metronidazole 1 g per rectum daily for 7 days or longer (some clinicians have added zinc sulphate 1% vaginal douches or vaginal washes with 3% acetic acid to the regimen)
    b. Metronidazole 2 g daily for 3 days to 5 days
    c. High dose intravenous metronidazole

4. High doses of oral tinidazole e.g. 2 g twice daily for 2 weeks, with or without intravaginal tinidazole

There are anecdotal reports of treatment success with the following regimens, most of which are not readily available in the UK. It should be noted that most of these are based on success in one or two patients, each of whom had previously received a wide variety of treatments. The definition of cure was variable and microbiological follow up was not available in all cases. Additionally for each case report of cure with specific treatment, there are reports of failure with the same agents. (**IV** or anecdotal).

- 6% Nonoxynol–9 pessaries nightly for 2 weeks and then once weekly for up to 7 months
- Acetarsol pessaries 2 x 250 mg nightly for 2 weeks
- Paromomycin sulphate 250 mg pessaries once or twice daily for 2 weeks

Management of Sexual Partners

- Current partners should be screened for the full range of sexually transmitted infections and treated for *T. vaginalis* irrespective of the results of investigations (**Ib, A**).
- In a male contact of *T. vaginalis*, found to have non-gonococcal urethritis (NGU) on screening, it is reasonable to treat initially for *T. vaginalis* and repeat the urethral smear before treating additionally for NGU (**III**).

***T. vaginalis* in Children**

Trichomonas may be acquired perinatally and occurs in about 5% of babies born to infected mothers. Infection in prepubescent girls is unusual. Infection beyond the first year of life should suggest sexual contact (although other modes of transmission are also postulated) and the child should be appropriately evaluated.

Follow up

Tests of cure are only recommended if the patient remains symptomatic following treatment, or if symptoms recur (**IV, C**).

Definitions:

Levels of Evidence

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- Indicates absence of directly applicable studies of good quality.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is graded and identified for select recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate diagnosis and effective treatment and management of *Trichomonas vaginalis* infection
- Most strains of *T. vaginalis* are highly susceptible to metronidazole and related drugs (approximately 95% cure rate).
- In clinical practice a cure rate of 92% was achieved in patients with refractory trichomoniasis treated with high doses of oral and vaginal tinidazole

POTENTIAL HARMS

- *With metronidazole*, patients should be advised not to take alcohol for the duration of treatment and for at least 48 hours afterwards because of the possibility of a disulfiram-like (Antabuse effect) reaction.
- Metronidazole enters breast milk and may affect its taste. The manufacturers recommend avoiding high doses if breast feeding.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The recommendations in this guideline may not be appropriate for use in all clinical situations. Decisions to follow these recommendations must be based on the professional judgement of the clinician and consideration of individual patient circumstances and available resources.
- All possible care has been undertaken to ensure the publication of the correct dosage of medication and route of administration. However, it remains the responsibility of the prescribing physician to ensure the accuracy and appropriateness of the medication they prescribe.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 Aug (revised 2007 Jan)

GUIDELINE DEVELOPER(S)

British Association for Sexual Health and HIV - Medical Specialty Society

SOURCE(S) OF FUNDING

Not stated

GUIDELINE COMMITTEE

Clinical Effectiveness Group (CEG)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Author: Jackie Sherrard, Department of Genitourinary Medicine, Churchill Hospital, Oxford

Clinical Effectiveness Group (CEG) Members: Keith Radcliffe (Chairman), Imtyaz Ahmed-Jushuf, David Daniels, Mark FitzGerald, Neil Lazaro, Gill McCarthy, Guy Rooney

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Declaration of personal interests: None

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GUIDELINE AVAILABILITY

Electronic copies: Available from the British Association for Sexual Health and HIV Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- UK national guidelines on sexually transmitted infections and closely related conditions. Introduction. Sex Transm Infect 1999 Aug;75(Suppl 1):S2-3.
- Revised UK national guidelines on sexually transmitted infections and closely related conditions 2002. Sex Transm Infect 2002;78:81-2

Print copies: For further information, please contact the journal publisher, BMJ Publishing Group.

Additionally, auditable outcome measures are available in the original guideline document.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on June 15, 2000. The information was verified by the guideline developer on October 13, 2000. This summary was updated by ECRI on June 24, 2002. This NGC summary was updated by ECRI Institute on December 12, 2007. The updated information was verified by the guideline developer on February 7, 2008.

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